GUIDE FOR ACQUIRING RADIATION MACHINES WHICH CAN OPERATE IN EXCESS OF 500 KVP

1.0 Summary

The California Code of Regulations require that every person who intends to acquire a radiation machine capable of operating at a potential in excess of 500 kVp shall notify the Department at least 60 days prior to taking possession of the machine or at least 60 days prior to the commencement of construction or reconstruction of the room which will house the machine, whichever occurs first.. They also require that the equipment shall not be used until the user has obtained written approval of the provisions for radiation safety from the Department and that a calibration of the output of each radiation therapy system shall be performed by a physicist approved by the Department before the system is first used to treat patients.

2.0 Shielding Evaluation

The physicist's report must include an accurate evaluation of the potential radiation exposure of individuals incident to the use of the therapy equipment under the stated assumed operating conditions. This is to assure that maximum permissible doses, specified in regulation, will not be exceeded. The evaluation must also include the location of the therapy equipment with reference to controlled and uncontrolled areas in the immediate vicinity, and assessment with respect to the need for system interlocks and radiation monitors. The physicist's report must contain, as appropriate, the elements below:

2.1 The name, address, and telephone number of the physicist who performed the design evaluation. If the work was performed under supervision, the name of the supervising physicist must also be stated.

2.2 The name, address, and telephone number of the contact person responsible for the installation.

2.3 The name, address, including building and room number, and telephone number of the medical facility.

2.4 Identification of the machine and major components thereof, to include manufacturer, model designation, specification of radiation types, and all energies available for clinical use.

2.5 Identification of any alternate treatment modalities that are to be used clinically.

2.6 Material and thickness of recommended shielding for all primary and secondary barriers to ensure compliance with 17 CCR Section 30305. Special requirements are contained in Title 24, CCR, Sections 3101C through 3104C.5, and 12-31C-1.

2.7 Recommendations on restriction of position or attitude of the therapy head.

2.8 Material and thickness of viewing windows.

2.9 Statement of operating assumptions on which barrier calculations were based, including workload, use, and occupancy factors.

2.10 When an alternate treatment modality is to be employed, a statement describing all operating assumptions specific to that modality, and their effect upon barrier calculations, must be provided.

2.11 Complete copy of actual barrier calculations.

2.12 The calculated radiation levels in the adjacent occupied areas under conditions of use (with scattering material in place).

2.13 Calculated instantaneous dose equivalent rates and maximum hourly and weekly dose to be received by personnel in the adjacent occupied areas under worse-case operating conditions.

2.14 Facility drawings: The architect's drawings, scale drawings, or carefully dimensioned sketches, including both plan and elevation with appropriate cross sections, showing the therapy room and all adjacent areas within and outside the building, must accompany the physicist's report. Drawings must include machine location and orientation, direction of North, target location, isocenter, the locations and sizes of all penetrations through each shielding barrier, and shielding thicknesses.

3.0 Survey Reports

Immediately following installation of the therapy machine, the user's physics consultant should be requested to establish the safe and proper operation of the machine and compliance with CCR 17, Section 30312(b). The physicist should prepare a detailed report of the findings for submission to the Department as outlined below.

3.1 Calibration Report for Therapy Equipment

3.1.1 The name, address, and telephone number of the physicist who performed the calibration verification tests, date the tests were performed, and signature of the physicist who performed them. If the work was performed under supervision, the name of the supervising physicist must also be stated.

3.1.2 Identification of the calibration report as one intended to fulfill the requirements of 17 CCR Section 30312 (b)(4).

3.1.3 The name, address, and telephone number of the medical therapist responsible for the machine.

3.1.4 The name, address, including building and room number where the machine is located, and telephone number of the medical facility.

3.1.5 Identification of the machine and major components thereof, to include manufacturer, model designation, serial number, specification of all radiation types, and maximum and all effective energies used for therapy applications.

3.1.6 Identification of the radiation measuring instruments used, including manufacturer, model designation, serial number, and latest calibration report.

3.1.7 Description of phantom used.

3.1.8 Depth at which machine calibration is specified and calibration conditions that describe the unique calibration conditions.

3.1.9 Exposure rate or dose rate for the range of treatment distance used clinically including typical and maximum monitor units per minute..

3.1.10 Specification of all correction, calibration, conversion, and backscatter factors used.

3.1.11 Evaluation of timer error or monitor end-effect, depending on the type of beam on controller.

3.1.12 Congruence between radiation field and the field indicated by the localizing device for the range of field sizes used. The method of measurement must be stated.

3.1.13 Mechanical check of gantry or collimator rotation accuracy

3.1.14 Alignment of isocenter with collimator, gantry rotation, and table movement; alignment of lasers and cross hair.

3.1.15 Uniformity of the radiation field as established by isointensity plots for the range of field sizes used for therapy, measured field flatness, and symmetry at specified depth.

3.1.16 Measured transmission factors for beam modifiers, such as wedges and trays; measured depth dose data.

3.1.17 Instructions for the proper and reproducible performance of periodic (daily or weekly) quality assurance checks that will permit the therapy equipment user to verify constancy of calibration.

3.1.18 Conclusion that machine is accepted for clinical use within the scope of commissioning.

3.2 Radiation Protection Survey Report for Therapy Equipment

3.2.1 The name, address, and telephone number of the physicist who performed the survey, date the survey was performed, and signature of the physicist who performed them. If the work was performed under supervision, the name of the supervising physicist must also be stated.

3.2.2 Identification of the survey as one intended to fulfill the requirements of 17 CCR Section 30312 (b)(5).

3.2.3 The name, address, and telephone number of the medical therapist responsible for the machine.

3.2.4 The name, address, including building and room number where machine is located, and telephone number of the medical facility.

3.2.5 Identification of the machine and major components thereof, to include manufacturer, model designation, serial number, specification of all radiation types, and maximum and all effective energies used for therapy applications.

3.2.6 Identification of the radiation measuring instruments used, including manufacturer, model designation, serial number, and latest calibration report.

3.2.7 Statement of all operating assumptions used in preparing the report, to include workload, use, and occupancy factors.

3.2.8 Statement of evaluation of interlock and limit switch function, warning signs and signals, and other regulatory postings.

3.2.9 Measurements of dose rates in all possibly occupied areas, representative of beam qualities, orientations, and field sizes to be used.

3.2.10 Summary of results including estimates of the maximum expected exposures to persons under assumed conditions and a statement as to the methods of calculations.

3.2.11 Statement regarding the integrity of protective barriers with respect to performance compared to design criteria and freedom from significant variations on thickness, composition, or voids which could compromise performance, and method used to verify protective barrier integrity.

3.2.12 Physicist's recommendations to the user for optimization of radiation safety.

3.2.13 Facility drawings: Scale drawings or sketches showing the therapy room and all adjacent areas within and outside the building, must accompany the physicist's report. Drawings must include machine location and orientation, target location, isocenter, and approximate location of all measurements taken.

3.2.14 Conclusion that machine is accepted for clinical use.

4.0 Completion of Registration

Submit Radiation Machine Registration Form, RH 2261, with the Calibration and Survey Reports.